Trans-NIH Adverse Event Steering Committee

Charge

Adverse events and other types of safety information emanating from clinical trials provide a vitally important body of knowledge fundamental to understanding toxicity, optimal dosing and contraindications of new experienced interventions as well as potential risk participants may face when enrolling in trials and other clinical research.

All principal investigators conducting clinical research are required to submit adverse event reports to a variety of local and federal entities such as IRBs, DSMBs, NIH, FDA, and OHRP. However, investigators, institutional administrators, and federal policy makers alike have largely recognized the difficulties posed by the diversity among the panoply of current reporting requirements. The wide variation in these requirements complicates understanding and fulfillment of investigator responsibilities and makes it difficult for institutions to develop streamlined procedures for the reporting and transmission of this critically important information.

The purpose of this Committee will be to guide CRpac efforts to provide a federal point of leadership in rectifying this problem. Discerning the magnitude and nature of this diversity in requirements will be a necessary first step. Consequently, the Committee's first charge will be to help gather and analyze (1) adverse event terms, definitions, and rules contained in regulations, policies, and guidance documents; (2) the workflow for reviewing and using adverse event information; and (3) the adverse event information (data) requirements of NIH.